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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,384

11/03/2005

Paul Leonard Greenhaff

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,384	<b>Applicant(s)</b> GREENHAFF ET AL.	
	<b>Examiner</b> Ganapathy Krishnan	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 58-111 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/03/05</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 recites, 'carnitine substance'. It is not clear what all are encompassed by the term substance. The metes and bounds are unclear. Therefore, the scope of the claim is indefinite as to what the term 'carnitine substance' is encompassed.

Claim 63 recites the terms, 'active derivative'. It is not clear what applicants intend by the term active. In the absence of the specific derivatizations to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of the derivatives of this invention, the identity of said derivatives would be difficult to describe and the metes and bounds of the said derivatives applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in this and all other claims in which the said terms are recited.

The term "simple" in claim 65 is a relative term which renders the claim indefinite. The term "simple" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification gives examples of simple carbohydrates

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but the degree of simplicity is not clear from these examples either. The said term is also recited in other claims.

Claim 72 recites the term substantially followed by ranges for the amounts of the active agents. It is not clear what substantially means. According to the amounts recited it appears that the agent is the one that is to be present in substantial amounts. Clarification is needed of the said term in this and all other claims in which the said term is recited.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58-63, 76-80 and 91-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al (EP 0680945; cited in IDS of 11/3/2005).

Davis teaches compositions comprising carnitine, glycine which is useful for carnitine absorption (amino acid; the agent; pages 5-6; Examples 1-7; limitations of claims 58-63; page 3, lines 16-21. Davis discloses the said composition in the form of an aqueous solution (page 3, lines 48-50; limitations of claims 74-80 and 91-92).

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Claims 58-65, 74, 76-83, 91 and 93-102 are rejected under 35 U.S.C. 102(b) as being anticipated by Pola (WO 01/95915; cited in IDS of 11/3/2005).

Pola teaches a food/dietary supplement comprising L-carnitine and acyl derivatives of L-carnitine and Ribose (a simple sugar; pages 6-9; pages 11-14; limitations of claims 58-65, 76-83). The composition can be in the form of syrup (page 12, line 3; limitations of claims 74, and 91). Pola teaches the administration of a solution comprising his composition to rats via injection. The results of this test shows that carnitine is absorbed by the tissue as evidenced by the number of ectopic contractions observed (page 5, Experimental through page 6, Table 2; limitations of claims 93-102).

Claims 93-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Bohles et al (J. Parenteral and Enteral Nutrition, 1984, 8(1), 9-13; cited in IDS of 11/3/2005).

Bohles teaches a method increasing carnitine retention by administration of amino acids, glucose (both insulin increasing agents) and L-carnitine to piglets (page 9, abstract and right column, see under Experimental Design). The administration is seen to produce increased energy gain and improvement in nitrogen balance, all of which indicate carnitine retention. This teaching is seen to meet the limitations of instant claims 93-103.

Claims 93-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al (Biochim. Biophys. Acta., 1993, 1170(3), 265-274; cited in IDS of 11/3/2005).

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Gross teaches the uptake and retention of carnitine by rats (abstract, page 266, right column, section entitled-Intestinal levels of carnitine through page 267). The study also deals with sodium dependent uptake. This teaching is seen to meet the limitations of instant claims 93-103.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 63-73, 84-90 and 104-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al (EP 0680945; cited in IDS of 11/3/2005) in view of Pola (WO 01/95915; cited in IDS of 11/3/2005), Bohles et al (J. Parenteral and Enteral Nutrition, 1984, 8(1), 9-13; cited in IDS of 11/3/2005) and Gross et al (Biochim. Biophys. Acta., 1993, 1170(3), 265-274).

The teaching of Davis, Pohles, Pola and Gross is explained above. However, the prior art above do not teach the use of carbohydrate derivatives, proteins, other sugars like fructose or derivatives thereof and the amounts of carnitine and the agent as instantly claimed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make composition including food supplements comprising carnitine or its derivatives, proteins and sugars like fructose and sugar derivatives and use them in a method of increasing carnitine retention since closely analogous compositions comprising carnitine and the additional agent to increase or stimulate insulin level is seen to be taught in the prior art.

One of ordinary skill in the art would be motivated to make the compositions as instantly claimed and use them in a method as instantly claimed since carnitine uptake and retention is shown in animals and suggested for humans (Gross et al, page 274, right column) and Pola teaches synergistic effect of carnitine and its derivatives and ribose sugar combination on myocardial insufficiency and muscle fatigue. Pola also suggests a 1:10 ratio of carnitine to sugar (page 3, line 2; and lines 3-17). One of skill in the art would look for other such combinations. It is well within the skill level fo the artisan to adjust the amounts of the active agents in order to optimize the beneficial effects.

***Conclusion***

Claims 58-111 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang, Ph.D./  
Supervisory Patent Examiner, Art Unit 1623

/Ganapathy Krishnan/  
Examiner, Art Unit 1623